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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,198	11/27/2001	Anders Bjorling	P01,0434	9390

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EXAMINER	
SCHAETZLE, KENNEDY	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 12/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,198	BJORLING ET AL.	
	Examiner	Art Unit	
	Kennedy Schaetzle	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,7,10-22 and 25-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *15-21,32-38 and 49-55* is/are allowed.

6)☒ Claim(s) *1,4,7,10-14,22,25,27-31,39-42,44-48,56 and 57* is/are rejected.

7)☒ Claim(s) *5,26 and 43* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 15 is objected to because of the following informalities: line 3 of claim 15 is grammatically awkward. Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 4, 7, 10-12, 22, 25, 27-29, 39-42, 44-46, 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (Pat. No. 5,193,535) in view of Glace (Pat. No. 5,158,092).

Concerning claim 1 and claims with similar limitations, Bardy discloses a method of detecting cardiac rhythm abnormalities comprising providing a plurality of electrodes, obtaining individual unipolar electrical signals from cardiac tissue via said electrodes (note col. 4, lines 41-52, etc.), said unipolar signals exhibiting a time relationship relative to each other (an inherent property), and analyzing the time relationship by determining whether one of said unipolar signals was obtained with a time offset relative to another of said unipolar signals (note col. 5, lines 1-20) and, if so, generating said signal indicating a cardiac rhythm abnormality dependent on an absolute value of the time offset (note col. 9, lines 40-50). Bardy does not, however, discuss the utilization of an electrode lead with a tip having a plurality of electrodes, and concomitantly does not discuss placing the tip in contact with cardiac tissue so that all of the electrodes are simultaneously in substantially fixed contact with the cardiac tissue. Glace discloses such an electrode lead as shown in Figs. 4a and 4b. In Fig. 1b, Glace shows another suitable embodiment of the lead for the practice of his invention comprising a lead body with a tip and ring electrode such as the type disclosed and used by Bardy (note col. 6,

lines 29-36). Glace teaches that the spacing of electrodes and impedance must be sufficiently low to separate local potentials from remote potentials (col. 5, lines 38-49) and provides the arrangement shown in Figs. 4a and 4b as an improved embodiment. Clearly since Glace shows not only the electrode arrangement discussed by Bardy in a related method, but also an improved electrode arrangement encompassing the presently recited tip electrode configuration, those of ordinary skill in the art would have seen the obviousness of modifying the lead of Bardy to take advantage of the superior arrangement shown and taught by Glace.

Related comments apply to claim 4.

Regarding claim 7, the examiner takes Official Notice that the detection of a maximum slew rate or a maximum negative derivative is an old and well-known method for detecting the occurrence of a cardiac waveform and establishing a fiducial point from which to compare other like obtained waveforms.

Regarding claim 10, note the rejection of similarly worded claim 1 above. Further note col. 11, lines 11-60 in regards to the use of a threshold for comparing unipolar signals thereto. As is well-known in the cardiac signal detecting arts, any detected signal meeting the basic threshold requirements can be considered to be a valid signal (in this case, R-wave) and thus suitable for further processing. An analysis result indicating a cardiac abnormality would necessarily depend on the outcome of this initial screening process.

Regarding claims 11, 12, 28, 29, 45 and 46, as stated above in the rejection of claim 1, Glace presents a superior electrode arrangement comprising dot-like electrodes with respective spacings between the electrodes being substantially equal. The reasons for combining the references are given above.

Regarding claims 22 and 25, note the rejection of claim 1 above.

Regarding claim 39, note again the rejection of substantially similar claim 1.

Regarding claim 56, the unipolar signal-detecting device of Bardy in view of Glace inherently would perform as recited. Glace, for instance, shows four signals being produced from four tip electrodes (see Figs. 4a and 5) as would be expected for a unipolar electrode arrangement.

Regarding claim 57 and the use of a QRS detector, note col. 11, lines 11-60, where the detection of an R-wave is considered the equivalent of detecting the QRS signal.

4. Claims 13, 14, 30, 31, 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy in view of Glace as applied to claims 1, 4, 7, 10-12, 22, 25, 27-29, 39-42, 44-46, 56 and 57 above, and further in view of Desai (Pat. No. 5,433,198).

Regarding claims 13 and 14 and claims with similar limitations, although Glace discloses an arrangement wherein the electrodes are disposed about the periphery of a disc sans a center electrode, those of ordinary skill in the art would have recognized the exact arrangement to be a matter of obvious design as long as the basic concept of the invention (i.e., allowing determination of the phase differences between electrodes as a result of the depolarization vector) was not interfered with. Desai disclose a related system wherein such an arrangement is incorporated (note for example Fig. 2B). To include a center electrode as shown by Desai to allow one to pinpoint the origin of a tachyarrhythmia such as disclosed in col. 10, lines 10-34 would have therefore been considered a matter of obvious design given their known use in related systems.

Allowable Subject Matter

5. Claims 5, 26 and 43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record does not disclose the combination of recited correlating, shifting and identifying steps.

6. Claims 15-21, 32-38 and 49-55 are allowed.

The prior art of record does not disclose storing a detection pattern for the individual unipolar electrical signals as a template and comparing subsequently obtained detections to the stored template to obtain a comparison result.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
December 1, 2004